

STATUS OF CLAIMS

Claims 1-27 are presently pending in the application. Claims 24-27 were previously withdrawn from consideration pursuant to a restriction requirement and are hereby cancelled. Claims 2 and 3 were previously cancelled. Thus, claims 1 and 4-23 are presently under examination. Applicants hereby amend claim 1. Support for the amendment to claim 1 is found, *inter alia*, in the claims as originally filed and in paragraphs [0004] to [0007] of the specification. Applicant submits that no new matter has been added.

REMARKS

Applicants note that the Examiner has withdrawn her previous rejections of the claims over the Zaffaroni et al., Bruck and Lee. The Examiner has made the following new rejections over newly cited prior art.

Rejection Under 35 U.S.C. §102(b) Under Crivello

Claims 1, 8-12, 14-17, and 21-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crivello (U.S. Pat. No. 4,584,356).

In response, Applicants respectfully traverse the rejection and its accompanying remarks. Crivello et al. does not teach the invention of the claims. Specifically, Crivello et al. fails to teach all of the elements of the present invention as claimed in amended independent claim 1, which is directed to an *implantable or insertable medical device* comprising (a) a *therapeutic agent* and (b) a *polymeric carrier region that comprises said therapeutic agent* and which releases said therapeutic agent upon administration to a patient, said polymeric carrier region comprising a silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units, wherein the device further comprises a *barrier region disposed over the carrier region*.

Crivello et al. fails as an anticipatory reference because it fails to disclose all of the features of the claimed invention. For a reference to anticipate a claim it must disclose *each and every element* of the claim. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978)(emphasis added).

Crivello et al. fails to teach an enabled implantable or insertable medical device. Crivello et al. fails to disclose a therapeutic agent. Crivello et al. fails to disclose a polymeric carrier region. Crivello et al. also fails to teach a barrier region disposed over the carrier region.

These deficiencies in Crivello et al. are not surprising since the invention of Crivello et al. is not at all directed to medical devices or coatings for medical devices. Rather, the reference is directed to methods for chemical synthesis of silicone-organic block copolymer through free-radical initiated polymerization. The invention of Crivello et al. is “based on the discovery that polyorganosiloxane polymers can be made having chemically combined free-radical precursor groups situated at regular intervals along the polymer backbone which on thermolysis serve as sites for free-radical initiation.” (Crivello et al., col. 1, lines 34-43). There is no enabling disclosure of a medical device or a drug carrier region or a barrier region whatsoever. Indeed, the passage that the Examiner turns to repeatedly to support his assertion that Crivello et al. teaches a medical device comprising a polymer that is “useful as a controlled release drug carrier” is the following general statement of potential wide-ranging applications for the materials produced according to the disclosed synthesis methods:

These silicone-organic block polymers can be used in a variety of applications such as thermoplastic elastomers, thermoplastics, impact modifiers, surface active agents, mold release agents, membranes, controlled release drug carriers, packaging, medical tubing, biomedical prothesis [sic], etc.

(Crivello et al., col. 5, lines 1-7).

This passage provides the *only* mention of the terms “drug,” “carrier,” and “medical” (for “medical tubing”) within the reference. Crivello et al. does not discuss a single specific therapeutic agent or drug. It provides no discussion of any medical device, much less one having the claimed structure with a carrier region and barrier region.

Applicants state that such statement is not an enabling disclosure of the elements of the claimed medical device of the present invention, either structurally or functionally. The reference offers no guidance about how to make and to use the disclosed compositions to achieve controlled delivery of drugs and thus, is by no means sufficiently enabled to be an anticipatory reference for the claimed invention. Indeed, even the Examiner states that “Crivello does not explicitly state that the copolymer is useful as a drug release coating on a medical

device.” He also states that “Crivello briefly states that the block copolymer is useful as a drug carrier but does not further elaborate.”

Given such deficiencies, Crivello et al. fails as an anticipatory reference. Claim 1 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(b) as anticipated by Crivello et al.

Rejection Under 35 U.S.C. §102(b) Under Kumar et al.

Claims 1, 8-19, and 21-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kumar et al. (U.S. Pat. No. 5,057,619).

In response, Applicants respectfully traverse the rejection and its accompanying remarks. For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

Like Crivello et al., Kumar et al. fails as an anticipatory reference because it does not teach all of the claimed features of claim 1 of the invention. Specifically, Kumar et al. fails to teach an implantable or insertable medical device. Kumar et al. fails to disclose a therapeutic agent. Kumar et al. fails to disclose a polymeric carrier region. Kumar et al. also fails to teach a barrier region disposed over the carrier region. Like Crivello et al., the Kumar et al. reference provides only a general statement of potential wide-ranging applications for the materials produced according to the disclosed synthesis methods. This statement is also what the Examiner relies upon in his rejection of the claims over Kumar (“Kumar exemplifies that polysiloxane-block copolymers...[has] uses [which] include controlled release drug carriers (column 4, lines 57-58)”).

The vinyl-siloxane block copolymers of the invention can be used in the areas of release coatings for pressure sensitive adhesives, surface active agents, permselective membranes, impact modifiers, fabric treatments, thermoplastic low temperature elastomers, controlled drug release carriers, packaging, medical tubing, biomedical prostheses [sic], etc.

(Kumar et al., col. 4, lines 52-59).

There is no disclosure of an actual drug or therapeutic agent in any of the materials disclosed. There is no disclosure of a medical device, either with or without the structural elements of the Applicants' medical device. There is no discussion of a medical device structured to have a carrier portion and a barrier portion. The cited passage is a non-enabled and general statement about the future potential for using the disclosed compositions for such varied uses as "controlled drug release carriers," "pressure sensitive adhesives," and "fabric treatments" and is by no means sufficiently enabled to be an anticipatory reference for the claimed invention. Indeed, the reference offers no guidance about how to make and to use the disclosed compositions to achieve controlled delivery of drugs.

Given the above, Applicants respectfully submit that Kumar et al. fails as an anticipatory reference. Claim 1 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(b) as anticipated by Kumar et al.

Rejection Under 35 U.S.C. §103(a)

Claims 4-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Crivello in view of Kamath et al., U.S. Pat. No. 6,335,029. Claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Crivello or Kumar in view of Zukosky et al., U.S. Pat. No. 4,616,064.

In response, Applicant respectfully traverses the rejections and their accompanying remarks. Applicants state that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some *suggestion or motivation*, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, *to modify the reference or to combine reference teachings*. Second, there must be a *reasonable expectation of success*. Finally, the prior art reference (or references when combined) *must teach or suggest all the claimed features*. In addition, the teaching or suggestion to make the claimed combination and

the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As indicated above with respect to the anticipatory rejection over Crivello et al., this primary reference fails to teach all of the claimed features. The secondary references do not remove the infirmities of Crivello et al.

The Examiner states that the “the claimed block copolymer is notoriously old.” As evidence, the Examiner turns to the sole mention of “siloxane polymers” in Kamath et al., a long list of polymeric materials that may be used to formulate a drug-eluting medical device. There is no disclosure of the claimed silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units.

Also, the Examiner has not shown that there is some suggestion or motivation in either Crivello et al. or Kamath et al. to modify the reference or to combine reference teachings. The Examiner has proffered no evidence that such knowledge is generally available to one of ordinary skill in the art. The Examiner has also failed to demonstrate that there would be a reasonable expectation of success if one of ordinary skill in the art were to somehow take the compositions of Crivello et al. and modify it to formulate a coating on a drug carrier as taught by Kamath et al. Thus, to make such a combination and make a conclusion of obviousness could only be based on the use of *undue* hindsight, which has long been held to be impermissible. MPEP 2142, second paragraph, and the cases cited therein. *See* especially, *Akso N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Claim 20 was rejected over either Crivello et al. or Kumar et al. in view of Zukosky et al. Zukosky et al. is cited by the Examiner for teaching medical tubing that can be radiation sterilized. It does not remedy the fundamental deficiencies of the primary references, Crivello et al. or Kumar et al., discussed above. As such, the combination of references fails to teach all of the claimed elements and thus, fails to provide a proper basis for a *prima facie* showing of obviousness.

For at least these reasons, Applicants respectfully submit that claims 4-7 and 20 are patentable over the cited references. Given the above remarks and the amendments to the

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claims, Applicant states that the Examiner's rejection under 35 U.S.C § 103(a) has been obviated and Applicant respectfully requests that the Examiner withdraw the rejections.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

FEES

The Office is authorized to charge any fees required to deposit account number 50-1047.

Respectfully submitted,

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